

# Exhibit C

**From:** Correll, William A <William.Correll@fda.hhs.gov>  
**Sent:** Friday, November 22, 2013 4:17 PM  
**To:** Whitmore, Arthur <Arthur.Whitmore@fda.hhs.gov>; Fabricant, Daniel <Daniel.Fabricant@fda.hhs.gov>; Karas, Douglas <Douglas.Karas@fda.hhs.gov>; Harris-Garner, Kerri L. <Kerri.Harris-Garner@fda.hhs.gov>  
**Cc:** Burgess, Shelly <Shelly.Burgess@fda.hhs.gov>; Natanblut, Sharon <Sharon.Natanblut@fda.hhs.gov>; Christin, Charlotte - OC <Charlotte.Christin@fda.hhs.gov>  
**Subject:** RE: USA Today question on another aegeline recall

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Please include Kerri Harris-Garner in CFSAN recall issue discussions. OC suggested change below.

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**From:** Whitmore, Arthur  
**Sent:** Friday, November 22, 2013 3:56 PM  
**To:** Fabricant, Daniel; Karas, Douglas; Correll, William A  
**Cc:** Burgess, Shelly; Natanblut, Sharon  
**Subject:** RE: USA Today question on another aegeline recall

that's good. thank you Dan. Shelly suggest we put the two together like this -

**We are aware of the Physique Enhancing Science (PES) of (insert city, state) voluntarily initiated recall and are following our standard procedures to document, classify, and monitor the recall. The exact role of aegeline in recent cases of liver damage is still being investigated. However, FDA has indicated that it considers aegeline a new dietary ingredient (NDI). Dietary supplements containing an NDI are considered adulterated unless they only contain dietary ingredients that have been present in the food supply and used as food in a form not chemically altered or unless there is a history of use or other evidence of safety that the dietary ingredient will reasonably be expected to be safe when used under the conditions recommended or suggested in the labeling of the dietary supplement containing the ingredient, coupled with the manufacturer or distributor providing the information to FDA, at least 75 days prior to marketing its products, on the basis that the firm concluded that its dietary supplement containing a new dietary ingredient will be reasonably expected to be safe. FDA did not receive notification from PES before it marketed its dietary supplement products containing aegeline as a dietary ingredient.**

**Therefore, dietary supplements containing aegeline being recalled by PES are considered adulterated.**

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**From:** Fabricant, Daniel  
**Sent:** Friday, November 22, 2013 3:45 PM  
**To:** Whitmore, Arthur; Karas, Douglas; Correll, William A  
**Cc:** Burgess, Shelly; Natanblut, Sharon  
**Subject:** Re: USA Today question on another aegeline recall

How's this?

The exact role of aegeline in recent cases of liver damage is still being investigated. However, as we've said prior aegeline is an ndi that should have been notified to the agency, as it wasn't those products containing aegeline are considered adulterated.

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**From:** Whitmore, Arthur  
**Sent:** Friday, November 22, 2013 03:31 PM  
**To:** Karas, Douglas; Correll, William A; Fabricant, Daniel  
**Cc:** Burgess, Shelly; Natanblut, Sharon  
**Subject:** USA Today question on another aegeline recall

Bill, Doug, Dan - the chain below details this inquiry from Allison Young of USAToday, which is looking for FDA info on a recall by the firm PES of two of its aegeline-containing products. We are asking for you review of a draft answer prepared by ORA comms people - last line of this email. It looks too bare bones to me, and it doesn't address the question as to whether PES' aegeline-containing products are implicated in any way by the current outbreak of liver damage. It would be nice if we could say NO, if we know that to be the case, and provide a bit more info if any is available to provide.

The reporter asks in her email below **Does FDA have any information about this recall? Or whether the products are implicated in the ongoing outbreak of liver issues?**

The draft ORA response is:

**We are aware of the recall and are following our standard procedures to document, classify, and monitor the recall.**

Arthur

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**From:** Burgess, Shelly  
**Sent:** Friday, November 22, 2013 2:53 PM  
**To:** Whitmore, Arthur  
**Subject:** FW: ORA Response: Media Inquiry; USA Today; A 2nd supplement company conducting aegeline recall

Arthur – Can you vet....

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**From:** Kwisnek, Stephanie  
**Sent:** Friday, November 22, 2013 2:41 PM  
**To:** Burgess, Shelly  
**Cc:** ORA Ext Rel  
**Subject:** ORA Response: Media Inquiry; USA Today; A 2nd supplement company conducting aegeline recall

Shelly

We are aware of the recall and are following our standard procedures to document, classify, and monitor the recall.

Please clear this response with CFSAN before sending to the reporter.

Thank you,

Stephanie Kwisnek  
ORA External Relations Staff

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**From:** Burgess, Shelly  
**Sent:** Wednesday, November 20, 2013 5:49 PM  
**To:** ORA Ext Rel  
**Cc:** Putnam, Juli Ann  
**Subject:** Media Query - USA Today - Deadline 11/21 10am A 2nd supplement company conducting aegeline recall

Hi folks! Do we have any information about the this recall yet? Please advise. Deadline 11/21 10am. Thanks in advance.

Outlet: USA Today  
Reporter: Alison Young  
Deadline 11/21 10am  
Background: She continues to write about dietary supplements.

PES (Physique Enhancing Science) and their supplements Enhanced and Alphamine.

It looks like the company that I was inquiring about last week – Physique Enhancing Supplements – is conducting a recall of two of their aegeline-containing products: Enhanced and Alphamine.

But the company hasn't returned any of my calls since last week, nor are they posting any recall details on their website. I just spoke again with the person answering the phone at the company who confirms there is a recall of the two products being mentioned in various forum postings, and he thinks they're working on updating their website. But he has nothing to provide (and took my message again).

Does FDA have any information about this recall? Or whether the products are implicated in the ongoing outbreak of liver issues? (see below)

<http://forum.bodybuilding.com/showthread.php?t=158376233>  
***Alphamine / Enhanced Recall Lot #s***

From another forum..

To: Valued PES Customers

Ref: Voluntary Return of Alphamine and Enhanced products

PES takes pride in delivering the highest quality products on the market today. Because of our commitment to quality we request the return of the below listed lots of Alphamine and Enhanced.

If customers have unused or opened containers of these products, we request that you to return them to where it was purchased. A full refund will be provided for all returned product.

These products contain the ingredient "aegeline". It is important to stress that PES have received no serious adverse events reported from either of these products but out of an abundance of caution we are requesting their return.

Alphamine Lot #'s (Distributed between 09/09/2013 – 11/12/2013)

- N09474 EXP: 08/2015
- N08447-B EXP: 08/2015
- N08448 EXP: 08/2015
- N08447-A EXP: 08/2015
- N07398 EXP: 07/2015
- N07397 EXP: 07/2015

Enhanced Lot #'s (Distributed between 2/4/13 – 11/5/13)

- N04238 EXP: 04/2015
- N01047 EXP: 03/2015
- N01046 EXP: 03/2015
- M11589 EXP: 02/2015
- M11588 EXP: 02/2015

Those with these batches should email PES for return and refund at [admin@pescience.com](mailto:admin@pescience.com)

*Last edited by stainlessstyle; Yesterday at 04:35 PM. **Reason:** added email*